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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/748,492	12/30/2003	E. C. Henley	050152/NHN.0085.US00	8733

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KIRKPATRICK & LOCKHART NICHOLSON GRAHAM LLP
HENRY W. OLIVER BUILDING
535 SMITHFIELD STREET
PITTSBURGH, PA 15222

EXAMINER

KRISHNAN, GANAPATHY

ART UNIT PAPER NUMBER

1623

DATE MAILED: 01/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/748,492

Applicant(s)

HENLEY, E. C.

Examiner

Ganapathy Krishnan

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 15 recites the terms soy protein material. Even though the specification provides a broad definition of the terms they cannot be read into the claims. The definition of the said terms should be recited in the claim.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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Claims 1, 3-7 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 27-28 and 30-32 of U.S. Patent No. 6,326,366 ('366 patent). Although the conflicting claims are not identical, they are not patentably distinct from each other because:

Instant claims 1 and 6 are drawn to a method of preventing or inhibiting urinary incontinence comprising administering to a human a composition comprising at least one isoflavones selected from genistein, daidzein, glycitein, biochanin A, formononetin, their naturally occurring glycosides and their conjugates in an effective amount. Claims 27 and 30 of the '366 patent are also drawn to a method of treatment of urinary incontinence comprising administering the same active agents.

Instant claim claims 3-5 recite limitations drawn to the dosage amount of the active agents. The dosage ranges in instant claims 3-5 overlap with the dosage ranges for the active isoflavones recited in claim 28 of the '366 patent.

Instant claim 7 recites limitation drawn to the source of the isoflavones. The same source is recited in claims 31-32 of the '366 patent.

It would have been obvious to one of ordinary skill in the art that the limitations of instant claims 1 and 3-7 are substantially overlapping with those of claims 27-28 and 30-32 of the '366 patent. Instant claims 1 and 3-7 should recite limitations that are patentably distinct from those of claims 27-28 and 30-32 of the '366 patent.

One of ordinary skill in the art would be motivated to use isoflavones in a method as instantly claimed since the active agents (isoflavones) are safer since they are not metabolized to the estrogenic equol.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Potter et al (US 6,326,366).

Potter teaches a method for inhibiting or preventing urinary incontinence comprising administering to a human a therapeutically effective amount of a composition containing isoflavone selected from genestein, glycitein, biochanin A, genistin, glycetin (genistin and glycitein are naturally occurring glycosides; col. 20, lines 3-15; lines 22-25; limitations of instant claim 1). The dosage of the active agents is about 20-1000mg (col. 20, lines 16-19, limitations of instant claims 2-5). The isoflavones can be administered individually or as a mixture (col. 20, lines 22-25; limitations of instant claim 6). The isoflavones can be from clover or soy (col. 20, lines 26-29; limitations of instant claim 7). The method of Potter et al involves the use of pharmaceutical compositions containing the active isoflavones and an excipient (col. 12, lines 44-45; limitation of claim 8). The compositions can be in the form of a capsule or a tablet (pill), a suspension or a solution (col. 11, lines 55-64; limitations of instant claims 9-10). The composition can be formulated for administration including subcutaneous, oral and transdermal modes (col. 11, lines 60-67; limitations of instant claims 11-13). The composition can also contain substances like starch or glucose or gelatin (a protein material), which are food ingredients (col. 12, lines 46-50; limitations of instant claims 14 and 15).

This teaching of Potter et al is seen to meet the limitations of instant claims 1-15.

Conclusion

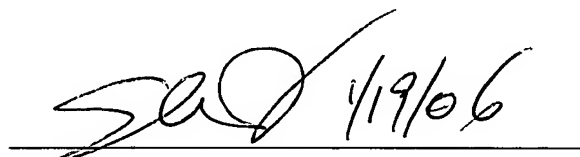
Claims 1-15 are rejected

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 571-272-0654. The examiner can normally be reached on 8.30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

GK



Shaojia A. Jiang
Supervisory Patent Examiner
Art Unit 1623